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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,861	12/09/2003	Amy L. Hammack	RADNT-035C	3531

7590 04/12/2007
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EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/730,861	Applicant(s) HAMMACK ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-52, 54, 56-59, 62-69 and 71-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-52, 54, 56-59, 62-69 and 71-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed February 14, 2007 have been fully considered but they are not persuasive. The claim limitation of the sensor being within a blood flow in the inferior vena cava without contacting the vessel wall is nebulous and dependent on the intended use as the size of the vena cava is variable and the distance is dependent on the size of the catheter. Thus the distance from the catheter is directly dependent on the catheter size and vessel size to properly place the temperature sensor.

The combination of Aliberto et al. and Diamantopoulos et al. clearly provide a heat exchanger with temperature sensing elements. The examiner's broad interpretation of affixed is a sensor that is not separable from the catheter. Further, the Applicant includes embodiments with sensors deployed from a lumen (Fig. 3b) as that of Aliberto et al. This clearly teaches the attachment of the sensor is not critical to the invention. The temperature sensors of Diamantopoulos et al. are affixed and teach deployment based on a memory material. The need to position the sensor in the blood flow and not in contact with the vessel wall is disclosed by U.S. Patent 4,830,013 to Maxwell, where the "wall effect" is discussed with clear emphasis on assuring the sensor will not contact the vessel wall. U.S. Patent 6,712,771 to Haddock et al. provides a teaching that the temperature of the blood may vary as much as two degrees from that of the vessel wall. These two teachings clearly would motivate a skilled artisan to keep temperature sensors away from a vessel wall.

Heat exchangers for blood are known, as are deployable temperature sensors for blood vessels. A skilled artisan would clearly be motivated to look to alternative temperature measurement techniques within this environment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-52, 54, 57-59, 62, 65, 66, 71-74 and 79-80 are rejected under 35

U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. and further in view of U.S. Patent 4,830,013 to Maxwell.

Aliberto et al. teach a catheter with heat exchange membrane, the catheter body including at least two lumens, and in the preferred embodiment the catheter body includes at least four lumens, two for fluid for temperature control and the others for holding a wire or wires that are attached to one or more distally-located sensors, such as temperature sensors, pressure sensors, gas sensors, and electrical sensors (Col. 4, lines 7-23). The heat exchange areas are disclosed as separate from the temperature sensor (Fig. 1, #s 68 & 100). The sensor is disclosed as a thermistor and can be disposed in a lumen of the catheter, or attached to a wire that is disposed in a lumen of the catheter, with the sensor hanging outside the catheter. This is broadly interpreted as a deployable temperature sensor as a skilled artisan would recognize that any appendage to a catheter would impede insertion of such device. Alternative temperature sensing is also disclosed (Col. 6, lines 27-39). In any case, the sensor is electrically connected to the coolant source for control of the temperature of the coolant (Col. 6, line 39) as described in U.S. Patent 6,019,783, incorporated by reference (Col. 3, line 33), which teaches multiple temperature sensors that can be thermistors, thermocouples, RTDs, or other temperature sensing element that can be orally or rectally placed in the patient or that can be mounted on the catheter or otherwise associated with the patient (e.g., the sensor can be an

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infrared device) to detect a temperature of the patient. Aliberto et al. does not disclose temperature sensors of nitinol and constrained. Diamantopoulos et al. teach a catheter for measuring vascular temperature using multiple thermistors (up to 10) on a nitinol (page 14, line 13) support that is resiliently biased (spring) and constrained by a sheath. The spring is affixed to the catheter. When the sheath is removed, the thermistor assumes a deployed position. Maxwell teaches the "wall effect", when a temperature sensor contacts a vessel wall, will impact a temperature reading and should be avoided, thus providing motivation to position sensors away from the vessel wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the thermistors on nitinol supports as taught by Diamantopoulos et al. in the invention of Aliberto et al. as an alternative means for deploying temperature sensors in blood vessels and to position the sensors away from a vessel wall as taught by Maxwell. A skilled artisan would be aware of the differential temperature between the vessel wall and the flowing blood and look to related art for means to negate such differentials.

Regarding claims 53, 65, 66 and 71, a sensor on a wire extendable from a lumen is interpreted as a deployable sensor controllable by an operator. The sensor being so placed would inherently be away from the heat exchange area.

Regarding claims 73 and 74, the disclosure of the sensor in a lumen that may extend out of the catheter inherently adds the step of displacing the sensor out of the catheter as disclosed.

Claims 56, 75 and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. in view of U.S. Patent 4,830,013 to Maxwell as applied to claims 49 and 73 above, and further in view of U.S. Patent 6,383,144 to Mooney et al. Aliberto et al. and Diamantopoulos et al. are discussed above, but do not teach deployment methods or memory materials. Mooney et al.

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disclose a catheter with a temperature sensor and a method for measuring a temperature, typically, of blood (abstract). Mooney et al. discloses a deployable sensor (Col. 13, line 33), the use of memory metals (Col. 12, line 11) and a self-deployment means (Col. 12, line 14) in a device for measuring the temperature within a vascular structure (Col. 14, line 42). Mooney et al. disclose a thermistor in a tubular probe with the sensor wires within the tubular portion (Fig. 1). The method of use is disclosed as inserting the sensor into a blood vessel and monitoring the temperature via an external device connected by wires to the sensor (Fig. 1). Mooney et al. teach memory metals for the probe and a potting material that releases (from constraint) the probe when within a body allowing the probe to take the shape of the memory material. This provides a self, or automatically, deploying probe. Nitinol is a well-known material for shaped memory. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory material and potting technique as taught by Mooney et al. in the device of Aliberto et al./Diamantopoulos et al./ Maxwell to provide alternative means for deploying a temperature probe without operator activity.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. in view of U.S. Patent 4,830,013 to Maxwell as applied to claim 49 above, and further in view of U.S. Patent 6,117,065 to Hastings et al. Aliberto et al., Diamantopoulos et al. and Maxwell are discussed above, but do not disclose an external lumen. Hastings et al teaches a catheter with an external lumen. The claimed use of an external lumen is not given patentable weight as lumens may be used for many purposes and devices. Further, the position of the temperature probe lumen (internal or external, full or partial length of the catheter) is not disclosed as being critical to its function as confirmed by multiple configurations being claimed in the application. It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to use an external lumen as taught by Hastings et al. in the device of Aliberto et al. in view of Diamantopoulos et al. in view of Maxwell as lumens are pervasive in the art and are well known to be of various sizes, shapes and locations.

Claims 67-69 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. in view of U.S. Patent 4,830,013 to Maxwell as applied to claims 49, 66 and 73 above, and further in view of WO 94/01177 to Hascoet et al. Aliberto et al., Diamantopoulos et al. and Maxwell are discussed above, but do not teach a pull wire deployment or a ramp for the deployment of the temperature sensor. Hascoet et al. teach a probe (catheter) having a shaft, an atraumatic tip (Fig. 1, # 551) and a heat exchange region defined by the fluid channels 872 and 874 (Page 14, lines 13-14). A temperature sensor is provided in an integral lumen (Fig. 8, # 892) that is deployable outward from the shaft by either a pull wire (Fig. 8, # 914) or a ramp like sloping member, 916a, to deflect the sensor in the proper direction (Fig. 8, # 916a). It is reasonable to interpret the ramp and probe as having complementary shapes to insure the proper movement of the probe as it is deployed. The sensor is deflected as an operator extends it from the lumen through an opening (aperture) in the side of the shaft. The sensor is disclosed as being deployable to 10 mm and therefore inherently capable of achieving 1.8 to 3.2 mm. Hascoet et al. disclose a fiber optic sensor with the fiber providing temperature information to the proximal end of the probe for control of the flow and/or temperature of the control liquid (Page 5, lines 33-40), strongly implying a closed loop controller for the heat exchange liquid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployment techniques as taught by Hascoet et al. in the invention of Aliberto et al. in view of Diamantopoulos et al. in view of Maxwell as Aliberto et al. clearly suggests temperature sensors

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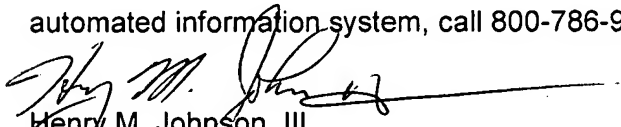
spaced from the heat exchanger and Hascoet et al. provides alternative means for positioning of temperature sensors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
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